IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORION CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Orion Corporation (hereinafter "Orion"), brings this action for patent infringement against Mylan Pharmaceuticals Inc. (hereinafter "Mylan"). This action concerns three patents relating to the carbidopa/levodopa/entacapone pharmaceutical, Stalevo®, a prescription drug used in the treatment of Parkinson's disease.

THE PARTIES

1. Plaintiff Orion is a Finnish company having an office and principal place of business at Orionintie 1A, 02200 Espoo, Finland. Orion is engaged in the business of research, development, and sale of pharmaceutical products. These products are sold throughout the world, including in the United States and the State of Delaware.

2. Upon information and belief, Mylan is a wholly-owned subsidiary of Mylan Inc., and has a principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

3. Upon information and belief, Mylan is in the business of, among other things, manufacturing, marketing, distributing, and selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

4. This action for patent infringement arises under the United States Patent Laws, Title 35, United States Code, including 35 U.S.C. § 271 and §§ 281-285. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

5. This Court has personal jurisdiction over Mylan because it purposefully avails itself of the privilege of selling its generic pharmaceutical products in the State of Delaware and can therefore reasonably expect to be subject to jurisdiction in the Delaware Courts. Among other things, upon information and belief, Mylan has expressly consented to jurisdiction by registering to do business in the State of Delaware and appointing an agent in Delaware for service of process (Exhibit A), and Mylan has marketing and sales activities in the State of Delaware, including but not limited to the distribution, marketing, and/or sales of generic pharmaceutical products to Delaware residents that are continuous and systematic. Moreover, upon information and belief, Mylan has invoked the benefits and protections afforded by the State of Delaware by bringing at least two lawsuits in this Court. Furthermore, this Court's personal jurisdiction over Mylan is proper because Mylan has consented to personal jurisdiction in this Court in the related case brought by Orion, Civil Action No. 11-78-GMS, which involves an entacapone product and one of the patents asserted to be infringed in this matter (i.e., U.S. Patent No. 5,446,194).

BACKGROUND

6. United States Patent No. 5,446,194 ("the '194 patent"), entitled PHARMACOLOGICALLY ACTIVE CATECHOL DERIVATIVES, was duly and legally issued to Orion-yhtymä Oy by the United States Patent and Trademark Office on August 29,

1995. The '194 patent is presently owned by Orion. A copy of the '194 patent is attached hereto as Exhibit B.

7. United States Patent No. 6,500,867 ("the '867 patent"), entitled PHARMACEUTICAL COMPOSITION COMPRISING ENTACAPONE, LEVODOPA, AND CARBIDOPA, was duly and legally issued to Orion Corporation by the United States Patent and Trademark Office on December 31, 2002. The '867 patent is presently owned by Orion. A copy of the '867 patent is attached hereto as Exhibit C.

8. United States Patent No 6,797,732 ("the '732 patent"), entitled PHARMACEUTICAL COMPOSITION COMPRISING ENTACAPONE, LEVODOPA, AND CARBIDOPA, was duly and legally issued to Orion Corporation by the United States Patent and Trademark Office on September 28, 2004. The '732 patent is presently owned by Orion. A copy of the '732 patent is attached hereto as Exhibit D.

9. Orion is the holder of a New Drug Application approved by the United States Food and Drug Administration ("FDA") for the use of carbidopa, levodopa and entacapone tablets in the treatment of Parkinson's disease.

10. Orion, through its partner Novartis, sells Stalevo® in the United States. Stalevo® is a combination of carbidopa, levodopa and entacapone approved by the FDA for the treatment of Parkinson's disease.

11. Upon information and belief, Mylan has filed with the FDA an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, importation, and sale of carbidopa, levodopa and entacapone tablets for the treatment of Parkinson's disease. Upon information and belief, Mylan filed the ANDA, assigned ANDA No. 203424, to obtain approval to market a generic version of

carbidopa, levodopa and entacapone before the expiration of the '194, the '867, or the '732 patent.

12. Upon information and belief, Mylan also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), certifications alleging, *inter alia*, that the claims of the '194, '867, and '732 patents are invalid, unenforceable, and/or will not be infringed.

13. Counsel for Mylan sent a letter ("the Notice Letter"), dated March 21, 2012, to Orion to notify Orion that Mylan had filed an ANDA for carbidopa, levodopa and entacapone tablets and was providing Orion with information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Orion received the letter on or after March 22, 2012.

14. The Notice Letter contained no allegation of non-infringement for one or more claims of the '194 patent.

15. Upon information and belief, Mylan's package insert will have the same indications and dosage instructions as those contained in the FDA-approved Stalevo® tablet product package insert.

COUNT I
(Infringement Of The '194 Patent)

16. Paragraphs 1-15 are incorporated herein by reference.

17. Under 35 U.S.C. § 271(e)(2)(A), Mylan infringed one or more claims of the '194 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '194 patent, of carbidopa, levodopa and entacapone tablets, a product the manufacture, importation, use, or sale of which would infringe one or more claims of the '194 patent.

18. Upon information and belief, Mylan will also induce or contribute to infringement of one or more claims of the '194 patent by actively aiding, abetting, encouraging,

and inducing, upon FDA approval, the sale of such a carbidopa, levodopa and entacapone tablet product together with instructions and labeling that will result in direct infringement of one or more claims of the '194 patent by ultimate users.

19. Orion will be substantially and irreparably damaged and harmed if Mylan's infringement is not enjoined. Orion does not have an adequate remedy at law.

COUNT II
(Infringement Of The '867 Patent)

20. Paragraphs 1-19 are incorporated herein by reference.

21. Under 35 U.S.C. § 271(e)(2)(A), Mylan infringed one or more claims of the '867 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '867 patent, of carbidopa, levodopa and entacapone tablets, a product the manufacture, importation, use, or sale of which would infringe one or more claims of the '867 patent.

22. Upon information and belief, Mylan will also induce or contribute to infringement of one or more claims of the '867 patent by actively aiding, abetting, encouraging, and inducing, upon FDA approval, the sale of such a carbidopa, levodopa and entacapone tablet product together with instructions and labeling that will result in direct infringement of one or more claims of the '867 patent by ultimate users.

23. Orion will be substantially and irreparably damaged and harmed if Mylan's infringement is not enjoined. Orion does not have an adequate remedy at law.

COUNT III
(Infringement Of The '732 Patent)

24. Paragraphs 1-23 are incorporated herein by reference.

25. Under 35 U.S.C. § 271(e)(2)(A), Mylan infringed one or more claims of the '732 patent by submitting to the FDA an ANDA seeking approval for the commercial marketing, before the expiration date of the '732 patent, of carbidopa, levodopa and entacapone tablets, a product the manufacture, importation, use, or sale of which would infringe one or more claims of the '732 patent.

26. Upon information and belief, Mylan will also induce or contribute to infringement of one or more claims of the '732 patent by actively aiding, abetting, encouraging, and inducing, upon FDA approval, the sale of such a carbidopa, levodopa and entacapone tablet product together with instructions and labeling that will result in direct infringement of one or more claims of the '732 patent by ultimate users.

27. Orion will be substantially and irreparably damaged and harmed if Mylan's infringement is not enjoined. Orion does not have an adequate remedy at law.

COUNT IV
(Declaratory Judgment On The '194 Patent)

28. Paragraphs 1-27 are incorporated herein by reference.

29. Upon information and belief, Mylan has made substantial preparations to sell carbidopa, levodopa and entacapone tablets labeled for the same indications and the same dosage and method of use as the Stalevo® product sold by Orion.

30. Upon further information and belief, Mylan further intends to commence sales of such carbidopa, levodopda and entacapone tablets immediately upon receiving approval from the FDA.

31. The manufacture, importation, use, sale, and offer for sale of carbidopa, levodopa and entacapone tablets so labeled, once approved by the FDA, will directly infringe,

induce and/or contribute to infringement of one or more claims of the '194 patent under 35 U.S.C. § 271 (a), (b), and/or (c).

32. Orion will be substantially and irreparably damaged and harmed if Mylan's threatened infringement is not enjoined. Orion does not have an adequate remedy at law.

COUNT V
(Declaratory Judgment On The '867 Patent)

33. Paragraphs 1-32 are incorporated herein by reference.

34. Upon information and belief, Mylan has made substantial preparations to sell carbidopa, levodopa and entacapone tablets labeled for the same indications and the same dosage and method of use as the Stalevo® product sold by Orion.

35. Upon further information and belief, Mylan further intends to commence sales of such carbidopa, levodopda and entacapone tablets immediately upon receiving approval from the FDA.

36. The manufacture, importation, use, sale, and offer for sale of carbidopa, levodopa and entacapone tablets so labeled, once approved by the FDA, will directly infringe, induce and/or contribute to infringement of one or more claims of the '867 patent under 35 U.S.C. § 271 (a), (b), and/or (c).

37. Orion will be substantially and irreparably damaged and harmed if Mylan's threatened infringement is not enjoined. Orion does not have an adequate remedy at law.

COUNT VI
(Declaratory Judgment On The '732 Patent)

38. Paragraphs 1-37 are incorporated herein by reference.

39. Upon information and belief, Mylan has made substantial preparations to sell carbidopa, levodopa and entacapone tablets labeled for the same indications and the same dosage and method of use as the Stalevo® product sold by Orion.

40. Upon further information and belief, Mylan further intends to commence sales of such carbidopa, levodopda and entacapone tablets immediately upon receiving approval from the FDA.

41. The manufacture, importation, use, sale, and offer for sale of carbidopa, levodopa and entacapone tablets so labeled, once approved by the FDA, will directly infringe, induce and/or contribute to infringement of one or more claims of the '732 patent under 35 U.S.C. § 271 (a), (b), and/or (c).

42. Orion will be substantially and irreparably damaged and harmed if Mylan's threatened infringement is not enjoined. Orion does not have an adequate remedy at law.

COUNT VII
(Exceptional Case)

43. Paragraphs 1-42 are incorporated herein by reference.

44. Mylan has proceeded with its unlawful activities with knowledge of the '194, '867 and '732 patents under 35 U.S.C. § 284.

45. This is an exceptional case warranting imposition of attorney fees against Mylan under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Orion respectfully requests this Court to enter judgment against Mylan as follows:

(a) finding that Mylan has infringed one or more claims of the '194, '867 and '732 patents by filing the aforesaid ANDA relating to Mylan's carbidopa, levodopa and entacapone tablets;

(b) prohibiting any approval by the FDA of Mylan's aforesaid carbidopa, levodopa and entacapone tablets on any effective date prior to the date of expiration of the latest to expire of the '194, the '867, or the '732 patent, or such later date as the Court may determine;

(c) declaring that Mylan will infringe one or more claims of the '194, '867 and '732 patents if Mylan's aforesaid ANDA relating to carbidopa, levodopa and entacapone tablets is approved and the approved product is sold and used in the United States;

(d) enjoining Mylan, its officers, agents, attorneys, and employees, and those acting in privity or concert with them or any of them, from the commercial manufacture, use, importation, or sale of a carbidopa, levodopda and entacapone tablet product labeled for use in treating Parkinson's disease until the expiration of the '194, '867 and '732 patents;

(e) finding that this is an exceptional case and granting Orion reasonable attorney fees pursuant to 35 U.S.C. § 285; and

(f) awarding Orion any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiff

OF COUNSEL:

Charles E. Lipsey
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
(571) 203-2700

Susan Haberman Griffen
Bryan C. Diner
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP.
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
(202) 408-4000

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